

**REMARKS**

Claims 1-29 are pending in the present application. In the Final Office Action, all claims were rejected. In response to the Final Office Action and concurrent with a Request for Continued Examination (RCE), claims 1, 7, and 28 have been amended. No new matter has been added. Reexamination and reconsideration of the pending claims as amended is respectfully requested.

As an initial matter, Applicants thank Examiner Schillinger for the courteous and helpful telephone interview conducted on March 4, 2009, with the undersigned attorney of record. During the interview, agreement was reached that the amendments contained herein distinguish the claimed invention from Barefoot.

Claim Rejections 35 U.S.C. § 102

In the Office Action, claims 1, 8-12, 14, 17 and 18 were rejected under 35 U.S.C. § 102(b) as being anticipated by Barefoot et al. (U.S. Patent No. 3,726,279). Such rejections are traversed in part and overcome in part for at least the following reasons.

Independent claim 1 recites:

A method of treating a stiffened blood vessel, said method comprising at least substantially encasing a stiffened portion of said blood vessel with an elastic membrane formed of biocompatible material, such that said membrane engages said stiffened portion of said blood vessel to thereby reduce the external diameter of said stiffened-portion of said blood vessel, passively carry at least a portion of blood pressure loads acting on said blood vessel throughout systole and diastole and reduce the effective stiffness of said stiffened portion of said blood vessel, said elastic membrane having a stiffness less than the stiffness of said stiffened portion of said blood vessel.

Barefoot fails to teach or suggest a method of treating a stiffened blood vessel. Barefoot discloses a hemostatic vascular cuff that is used to control hemorrhaging of suture lines in vessels following vascular surgery (Abstract; col. 4, lines 19-21). The only other application of Barefoot's vascular cuff is described in column 4, lines 12-13, as reinforcing the walls of diseased or damaged vessels. Barefoot does not disclose, teach or suggest using his cuff to treat

a stiffened blood vessel by encasing a stiffened portion of the blood vessel, as recited by claim 1. Moreover, the cuff in Barefoot encircles and remains secured to a blood vessel during vessel expansion and contraction. The cuff continually exerts gentle pressure against the vessel (Abstract). Barefoot fails to teach or suggest that his cuff reduces the external diameter of the stiffened-portion of the blood vessel, as is also recited by claim 1. Therefore, Barefoot fails to teach or suggest each and every element of the invention as recited in claim 1.

Nevertheless, in order to clarify the distinction between the present invention and the described applications of Barefoot's vascular cuff, claim 1 has been amended to recite in part that the method reduces the effective stiffness of said stiffened portion of said blood vessel, said elastic membrane having a stiffness less than the stiffness of said stiffened portion of said blood vessel. Support for this amendment may be found in paragraphs 0079, 0080 and 0081 of the application as published, therefore no new matter has been added. Reducing the effective stiffness of the vessel restores the vessel's ability to elastically expand and relax during systole and diastole in a similar manner to a healthy blood vessel. This ability is lacking in a stiffened blood vessel. Barefoot fails to teach or suggest this feature of the claimed invention.

Barefoot seeks to control hemorrhaging of a sutured vessel by reinforcing the sutured portion of the vessel. The reinforcement reduces expansion of the sutured portion so that the suture lines will not open up and allow bleeding (Abstract; col. 4, lines 1-11; col. 4 lines 19-21). Accordingly, Barefoot's vascular cuff would seem to have the result of increasing the effective stiffness of the vessel, contrary to what is recited in claim 1. It would also follow that the stiffness of the material from which the cuff is formed, which is described as including a semi-rigid core formed from a resilient material such as nylon or polypropylene (col. 1, lines 32-35; col. 3, lines 4-6) would have a stiffness greater than that of the encased portion of the sutured vessel.

Therefore, because the cited reference fails to teach each and every element of the claimed invention, anticipation cannot be established under 35 U.S.C. § 102(b). Applicants respectfully request withdrawal of the § 102(b) rejection and allowance of independent claim 1 and the claims depending therefrom.

Independent claim 28 has similarly been amended as claim 1, therefore for at least the same reasons as discussed above, Applicants respectfully request withdrawal of the §102(b) rejection of claim 28 and the claims depending therefrom.

Claim Rejections – 35 U.S.C. § 103

Barefoot in view of Khanghani

Claims 2-4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Barefoot in view of Khanghani et al. (U.S. Patent No. 6,984,201). Such rejections are overcome for at least the following reasons.

Claims 2-4 depend from independent claim 1 which has been distinguished from Barefoot as discussed above. Khanghani fails to provide the elements missing from Barefoot.

Khanghani discloses a blood circulation assistance device for location around a blood conduit (Abstract). The device has an inflatable bladder that is moveable between a contracted form and an expanded form for compressing the blood conduit to provide counterpulsation (Abstract). When the bladder moves from the contracted form to the expanded form at diastole, the blood conduit is compressed and blood in the conduit is displaced, thereby reducing cardiac loading (col. 9, lines 20-29). Khanghani fails to teach or suggest a method of treating a stiffened blood vessel. Moreover, the cited reference also fails to teach or suggest encasing a stiffened portion of the blood vessel. Additionally, Khanghani's device actively inflates and deflates, therefore Khanghani also fails to teach or suggest passively carrying at least a portion of the blood pressure loads, as recited by claim 1. Furthermore, because Khanghani's inflatable bladder displaces blood in the vessel during diastole, the bladder must be stiffer than the blood vessel to overcome the diastolic pressure therein, and hence Khanghani also fails to teach or suggest reducing the effective stiffness of the stiffened portion of the blood vessel, as recited by amended claim 1.

Because the cited references alone or in combination fail to teach each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claims 2-4.

Barefoot in view of Chuter

Claims 5, 6, 28 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Barefoot in view of Chuter (U.S. Patent No. 5,387,235). Such rejections are overcome for at least the following reasons.

Claims 5 and 6 depend from independent claim 1 and claim 29 depends from claim 28. Both claims 1 and 28 have already been distinguished from Barefoot as discussed above. Chuter fails to provide the elements missing from Barefoot.

Chuter discloses a prosthesis for treating an aneurysm (Abstract), not a method for treating a stiffened blood vessel. Chuter's prosthesis is disposed internally in a vessel (Fig. 15) therefore Chuter's device does not encase a stiffened portion of the blood vessel, nor does his device reduce external diameter of the stiffened-portion of the blood vessel and reduce the effective stiffness of the stiffened portion of the blood vessel, as recited in independent claims 1 and 28.

Because the cited references fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claims 5, 6, 28 and 29.

Barefoot in view of Von Oepen

Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Barefoot in view of Von Oepen (U.S. Patent Publication No. 2002/0151959). Such rejections are overcome for at least the following reasons.

Claim 7 has been amended to clarify the state of the stiffened portion of the blood vessel prior to treatment. Support for this amendment may be found in paragraphs 010 and 011 of the application as published, therefore no new matter has been added.

Claim 7 depends from claim 1 which has already been distinguished from Barefoot as discussed above. Von Oepen fails to provide the elements missing from Barefoot.

Von Oepen discloses a radial expandable stent (Abstract). Von Oepen fails to teach or suggest encasing a stiffened portion of a blood vessel with an elastic membrane as recited in claim 1. Moreover, Von Oepen's stent is positioned inside a blood vessel and

therefore it does not reduce the external diameter of the stiffened blood vessel, nor does it passively carry at least a portion of blood pressure loads. Because the purpose of a stent is to provide scaffolding to a vessel, it cannot reduce effective stiffness of the stiffened portion of the blood vessel, as also recited in the claim.

Because the cited references alone or in combination fail to teach or suggest each and every element of claim 7, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claim 7.

Barefoot in view of Spaulding

Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Barefoot in view of Spaulding (U.S. Patent No. 5,304,200). Such rejections are overcome for at least the following reasons.

Claim 13 depends from base claim 1 which has already been distinguished from Barefoot as discussed above. Spaulding fails to provide the elements missing from Barefoot.

Spaulding discloses a radial expandable endoprosthesis or stent (Abstract). Spaulding fails to teach or suggest encasing a stiffened portion of a blood vessel with an elastic membrane as recited in claim 1. Moreover, Spaulding's stent is positioned inside a blood vessel and therefore it does not reduce the external diameter of the stiffened blood vessel, nor does it passively carry at least a portion of blood pressure loads. Because the purpose of a stent is to provide scaffolding to a vessel, it cannot reduce effective stiffness of the stiffened portion of the blood vessel, as also recited by the claim.

Because the cited references alone or in combination fail to teach or suggest each and every element of claim 13, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claim 13.

Barefoot in view of Jones

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Barefoot in view of Jones (U.S. Patent No. 4,202,349). Such rejections are overcome for at least the following reasons.

Claim 15 depends from base claim 1 which has already been distinguished from Barefoot as discussed above. Jones fails to provide the elements missing from Barefoot.

Jones discloses radiopaque blood vessel markers (Abstract). The markers are attached to a blood vessel in order to allow verification of pulsatile blood flow under fluoroscopy by observing movement of the markers (Abstract). Therefore, Jones fails to teach or suggest a method of treating a stiffened blood vessel or encasing a stiffened portion of the blood vessel with an elastic membrane. Moreover, Jones also fails to teach or suggest reducing external diameter of the stiffened-portion of the blood vessel, reducing effective stiffness of the blood vessel or carrying at least a portion of the blood pressure loads, all recited in the claim.

Because the cited references alone or in combination fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claim 15.

Barefoot in view of Dusbabek

Claim 16 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Barefoot in view of Dusbabek et al. (U.S. Patent Publication No. 2001/0007082). Such rejections are overcome for at least the following reasons.

Claim 16 depends from claim 1 which has already been distinguished from Barefoot as discussed above. Dusbabek fails to provide the elements missing from Barefoot.

Dusbabek discloses a stent delivery system for maintaining patency of a vessel (Abstract; page 1, paragraph 0003), not a method of treating a stiffened blood vessel. The system is placed inside a blood vessel and thus Dusbabek's system does not encase a stiffened portion of the blood vessel, nor does it reduce the external diameter of the stiffened blood vessel and reduce the effective stiffness of the stiffened portion of the blood vessel, as recited in claim 1.

Because the cited references alone or in combination fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claim 16.

Barefoot

Claims 19-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Barefoot. Such rejections are overcome for at least the following reasons.

Claims 19-24 depend from independent claim 1 which has been amended and distinguished from Barefoot as discussed above.

Therefore, for at least the same reasons previously discussed above, Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claims 19-24.

Barefoot in view of Silvestrini

Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Barefoot in view of Silvestrini et al. (U.S. Patent No. 4,834,755). Such rejections are overcome for at least the following reasons.

Claims 25 and 26 depend from independent claim 1 which has been amended and distinguished from Barefoot as discussed above. Silvestrini fails to provide the elements missing from Barefoot.

Silvestrini discloses a braided prosthesis for use as an artificial ligament or tubular prosthesis (Abstract). Silvestrini's device, when used as a vascular prosthesis, is used to replace a section of a blood vessel. Therefore, Silvestrini fails to teach or suggest encasing a stiffened portion of the blood vessel and reducing the external diameter of the stiffened portion of the blood vessel. Moreover, Silvestrini also fails to teach or suggest reducing the effective stiffness of the stiffened portion of the blood vessel.

Because the cited references alone or in combination fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claims 25 and 26.

Barefoot in view of Barath

Claim 27 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Barefoot in view of Barath (U.S. Patent Publication No. 2002/0116016). Such rejections are overcome for at least the following reasons.

Claim 27 depends from independent claim 1 which has been distinguished from Barefoot as discussed above. Barath fails to provide the elements missing from Barefoot.

Barath discloses a coupling apparatus for creating a vascular anastomosis (Abstract), not a method for treating a stiffened blood vessel. The coupling apparatus is placed between a first blood supplying hollow organ and the side wall of a second hollow organ (Abstract). Because Barath's device is placed between two hollow organs, Barath fails to teach or suggest encasing a stiffened portion of the blood vessel or reducing the external diameter of the stiffened portion of the blood vessel. Moreover, Barath also fails to disclose, teach or suggest reducing the effective stiffness of the stiffened portion of the blood vessel.

Because the cited references alone or in combination fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claim 27.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

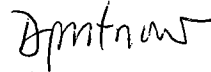


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PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

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